

DETAILED ACTION

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claims 28-35 are not subject to the Restriction Requirement since they were cancelled by Applicant.

Lack of Unity – Three Groups of Claims

Group I, claim(s) 1-9, drawn to a method of inhibiting a ubiquitin isopeptidase in a cell.

Group II, claim(s) 10-22, drawn to a method of treating or alleviating an oncological malady in a subject.

Group III, claims 23-27, drawn to a pharmaceutical composition suitable for treating an oncological malady in a human subject.

Group IV, claims 36-45, drawn to a method of treating a disorder mediated by a proteasome pathway in a patient, comprising administering to said patient an effective amount of a ubiquitin isopeptidase inhibitor.

The inventions listed as Groups I, II, III and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: an inhibitor of ubiquitin isopeptidase is not novel (see The Journal of Biological Chemistry, Vol. 276, No. 44, page 40585 last paragraph). Therefore, a holding of lack of unity amongst the inventions of Groups I-IV is proper.

Election

This application contains claims directed to more than one species of the generic invention. In addition to the election of Groups I-IV, the following specie election is also required. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, if applicant elects Group I or II, applicant is required to define one compound (see instant claims 8, 9, 18 and 19). With the election of Group II, applicant is required to elect one oncological malady (see instant claim 22). With the election of Group III, applicant is required to elect one antineoplastic agent (see instant claims 26 and 27). With the election of Group IV, applicant is required to elect one disorder (see instant claims 36-45).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement is traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election with traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that is the case. In

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either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election/Restriction Proper

MPEP 809.02(d) states "[w]here only generic claims are presented, no restriction can be required except in those applications where the generic claims recite such multiplicity of species that an unduly extensive and burdensome search is necessary." Here, the claims recited such a multiplicity of species that an unduly extensive and burdensome search would be necessary if all of the claimed species were to be examined simultaneously.

The inventions above are patentably distinct. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement and double patenting issues. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious the other group. Finally, the consideration for patentability is different in each case. Thus, it would be undue burden to examine all of the above inventions in one application and the restriction for examination purposes as indicated above is deemed proper.

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder Notice

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

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patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Ardin H Marschel/
Supervisory Patent Examiner, Art Unit 1614

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